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The objective of the present program of research is to study physiological processes that may mediate the links between psychological states and cancer. Specifically, the present study is designed to conduct an investigation of the cross-sectional associations between indices of stress reactivity and psychological coping styles in women with breast cancer and matched healthy controls. The aims of the project are: (1) to quantify parameters of biological reactivity to a behavioral stress paradigm in women with and without breast cancer; (2) To examine (a) group differences between women with and without breast cancer biological stress reactivity, and (b) the effects of menopause and familial risk on biological stress reactivity and emotional expression; and (3) To develop the methodology and obtain preliminary data which could justify subsequent, prospective research with high-risk populations. During the current reporting period, a new recruitment site has been added; 59 new subjects have been recruited in to the study; 51 assessments of research subjects have been completed; and preliminary (descriptive) analyses have been conducted on 35 subjects. The study relational database has been continuously updated, and biosamples have been stored at - 70 degrees C for assays.

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## Table of Contents

INTRODUCTION:

The broad objective of the present program of research is to study physiological process that may mediate the links between psychological states and cancer. Specifically, the present study is designed to conduct an investigation of the cross-sectional associations between indices of stress reactivity and psychological coping styles in women with breast cancer and matched healthy controls. The aims of the project are: (1) To quantify parameters of biological reactivity to a behavioral stress paradigm in women with and without breast cancer; (2) To examine (a) group differences between women with and without breast cancer in biological stress reactivity, and (b) the effects of menopause and familial risk on biological stress reactivity and emotional expression; and (3) To develop the methodology and obtain preliminary data which could justify subsequent, prospective research with high-risk populations.

BODY (Statement of Work):

A. Recruitment and Assessment – During the first nine months of this reporting period, subjects were recruited from the University of California, Irvine, Chao Comprehensive Cancer Center. During the final three months of this reporting period, an additional site – The Breast Care Center, Orange, California, was used to recruit research participants. This additional site was selected and utilized because the recruitment rate at the UC Irvine site was less than optimal, because this additional site provides clinical care to a large population of women with breast cancer, it is conveniently located only 1.5 miles from the UC Irvine Medical Center, and the sociodemographic profile of its patient population closely resembles that of patients at UC Irvine.

   During the current reporting period, 59 new subjects have been recruited into the study and 51assessments have been completed as of 9/30/03.

B. Database – All data, including clinical, sociodemographic, psychosocial, and physiological, have been continuously entered using SPSS (11.5) software. Checks for accuracy and reliability have been completed for the first 35 subjects.

C. Hormone Assays – Biosamples (e.g., plasma and salivary cortisol) have been collected, processed and frozen at - 80 degrees C for biochemical assays.

D. Data Analyses – Preliminary (descriptive) data analyses have been conducted on 35 subjects, as reported below.

KEY RESEARCH ACCOMPLISHMENTS:

A. Since the last report, we have recruited 59 new study subjects and completed 51 new study assessments. Preliminary (descriptive) analyses have been conducted on 35 subjects (23 participants for the Breast Cancer (BC) group, and 12 participants for the Healthy Control (HC) group).

B. We have incorporated an additional recruitment site (Breast Care Canter, Orange) and also an additional data collection site located at the UC Irvine main campus, since the UC Irvine General Clinical Research Center (existing data collection site ) has acquired new space and facilities on campus. This has facilitated a significant increase in our recruitment rate and the scheduling and assessment of subjects who live or work closer to this location.

C. We have recruited and trained 2 additional research assistants in preparation and response to growth in recruitment.

D. We recently sent out 210 letters to potential subjects who are or were recent patients of the Breast Care Center and meet study eligibility criteria . We have heard back from 72 women so far. Of these, 78% have indicated interest in learning more about the study with a view to considering participation. We expect to receive additional responses over the next few weeks.

REPORTABLE OUTCOMES:

Descriptive Statistics of Variables of Interest (N=35)

A. Key socio-demographic variables of BC (n = 23) and HC group (n = 12)
   - The age range of BC group is between 36-80 years of age, compared to 34-68 of the HC group.
   - The majority (70% and 67% for BC and HC group respectively) of the participant population is non-Hispanic White.
   - The majority of the participant population is married, with some college-level education, and an annual household income of greater than $60,000.
   - Over 50% of the BC participants are employed full-time, and over 75% of the HC participants are employed full-time.

B. Distribution of key biomedical variables for study
   - Reproductive history for BC group
     - The average age of first menstrual period is 12.02
     - 19 (83%) of the 23 women have been pregnant at least once, with an average of 3 pregnancies.
     - The average age of first pregnancy is 24.5
     - 13 (57%) of the 23 participants have used oral contraceptives at some point in their lives; of those, they have used it for 5 years on average
     - Excluding tamoxifen, 39% of the participants have used other HRT (hormone replacement therapy) some time during their lifetime for an average of 7 years
   - Family history of cancer in the BC group
     - Of 23 participants, 13 (56%) of them have at least one female relative who had also been diagnosed with breast cancer, while only 3 (13%)

have one relative who had been diagnosed with cervical or ovarian cancer
    - Of 23 participants, 17 (84%) of them have at least one relative who had been diagnosed with other forms of cancer (e.g., lung, prostate)
- Reproductive history for HC group
    - The average age of first menstrual period is 11.6
    - 9 (75%) of the 12 participants have been pregnant at least once, with an average of 3 pregnancies.
    - The average age of first pregnancy is 22
    - 9 (75%) of the 12 participants have used oral contraceptives at some point in their lives; of those, they have used it for 6.2 years on average
    - 6 (50%) of the participants have used other HRT (hormone replacement therapy) some time during their lifetime for an average of 11 years
- Family history of cancer in the HC group
    - Of 12 participants, 6 (50%) of them have at least one female relative who had also been diagnosed with breast cancer, while only 2 (16.7%) have one relative who had been diagnosed with cervical or ovarian cancer
    - Of 12 participants, 8 (66%) of them have at least one relative who had been diagnosed with other forms of cancer (e.g., lung, prostate)
- Distribution of Coping Styles of the BC and HC group
    - Coping style is based on the scores of the Marlowe Crowne Social Desirability Scale (MCSD) and the Taylor Manifest Anxiety Scale (TMAS).
    - The reliability of both the MCSD and TMAS scales are good (Cronbach's alpha at .75 and .65 respectively for each scale)
    - For the BC group
        - 14 out of 23 individuals are categorized as repressive copers (meaning that they scored high on the MCSD but low on the TMAS)
        - There are 2 individuals who have a defensive (high on both MCSD and TMAS) coping style and 7 who have a truly low anxious coping style (low on both MCSD and TMAS)
    - For the HC group
        - 7 out of 12 individuals are categorized as repressive copers
        - 4 individuals have a truly low anxious coping style

C. Preliminary analysis of cardiovascular reactivity data
- Mean heart rate increase is calculated based on the difference between mean baseline heart rate and mean peak heart rate during the TSST. For the BC group, the mean heart rate increase value is 14.57, and for the HC group, it is 15.31.
- Area under the curve for heart rate changes from pre-TSST (30 minutes pre-TSST), through the TSST (15 minutes), and until the end of recovery period (30 minutes after TSST) was calculated for each group. The mean value of 6751.98 was calculated for the BC group and 5576.54 for the HC group.

CONCLUSIONS:

- Descriptive statistics provide emerging evidence of reliability and sufficient variability in data to enable tests of the study hypotheses.
- Although descriptive statistics of key variables of interest have been listed, comparisons are not performed at this time because of the modest overall sample size and the disparity in sample size between groups.
- The addition of the new recruitment site will ensure all data is collected within the time-line described in the statement of work.

REFERENCES

None

APPENDICES

None